UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 29, 2010

MEMORANDUM

Subject: Protocol Review for Vaprox Hydrogen Peroxide Sterilant; Reg. No. 58779-4; DP Barcode: D382217.

From: Ibrahim Laniyan, Microbiologist
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Thru: Tajah Blackburn, Team Leader
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11/29/10

To: Zebora Johnson
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Steris Corporation
7405 Page Avenue
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I. BACKGROUND

Steris Corporation submitted for review, a protocol intended to show effectiveness of Vaprox Hydrogen Peroxide Sterilant against Mouse parvovirus. The intention is to add data, upon approval, to support claims for Mouse parvovirus when the product is vaporized using Steris vaporized hydrogen peroxide generation system in sealed enclosure of approximately 900 liters in volume.

This data package contained letter from the applicant (dated August 6, 2010), a copy of the protocol, and a draft copy of proposed label (dated 5/19/10).

III. BRIEF DESCRIPTION OF THE PROTOCOL

1. Objective

This protocol is designed to substantiate virucidal effectiveness claims of Steris' vaporized hydrogen peroxide (VHP) technology using hard non-porous surfaces within sealed enclosures. It determines the potential of the test agent to disinfect hard surfaces contaminated with Mouse parvovirus.

2. Protocol

Two product lots of product, Vaprox Hydrogen Peroxide Sterilant, will be tested against Mouse parvovirus. The stock virus culture will be adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus will be prepared by spreading 0.4 mL of virus inoculum uniformly over 4 in^2 of sterile glass slide. The virus films will be dried at ambient temperature. Fifteen (15) carriers will be tested per product lot. For each lot of product, carriers will be placed in the enclosure to be sealed and the sterilization will be conducted using Steris' VPH 1000 Ed generator. After completion of the cycle, the carriers will be processed within 2 hours. Following complete sterilization cycle, virus will be scraped from the surface of individual carrier in the presence of neutralizer, collected, and assayed for the presence of infectious virus. The cultures will be incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures will be microscopically scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls will include those for input virus titer, viability, dried virus count, plate recovery, cytotoxicity, column titer, and neutralization.

III. COMMENTS ON THE PROTOCOL

1. After sterilization cycle, the registrant proposed to use one recovery control to be processed immediately after drying step and one recovery control to be held alongside with the test. The Agency found those numbers of recovery control inappropriate for the number of carriers to be treated. **At least two (2) carriers must be processed immediately after drying step and at least two (2) carriers will be held alongside per test run (per lot tested)**; Total of at least eight (8) recovery control for both lots.

2. On page 5 of the proposed protocol, change "...the treatment area at **30°C+10°C**." to read "...the treatment area at **30±10°C**."

3. The submitted protocol, Virucidal Effectiveness Test on Mouse parvovirus using Steris' Vaporized Hydrogen Peroxide (VPH) Technology, will be acceptable once the above corrections will be made.